Site Specific Continuing review for sites relying upon the University of Chicago IRB. This form should be completed by each relying site.

University of Chicago Protocol #:

Protocol Title:

Relying Site Name:

Relying Site Investigator:

Relying Site Email address:

Name of Individual Completing Form:

Role on Study:

Date:

I. Study Status

1. Enrollment Status at Site:
   - ◯ Enrollment Open
   - ◯ Enrollment Permanently Closed
   - ◯ Enrollment Temporarily Halted or Suspended
   - ◯ No direct subject interaction - Study approved only for collection of data/samples (ongoing)
   - ◯ No direct subject interaction – collection of data/samples complete

2. If applicable, please explain why enrollment is halted or suspended. Please attach any documentation regarding the halting or suspending of enrollment.

3. Current Study Status at Site:

- ◯ Research has not begun/no subjects have been enrolled and/or no records or data analyzed
- ◯ Research related interventions/activities on-going
- ◯ Long-term Follow-up only - (all subjects have completed all research related interventions/activities)
- ◯ Chart review/specimen analysis on-going
- ◯ Data Analysis Only (no further subject interaction and no further data collection)
- ◯ Closed - Awaiting Closeout or Other (Answer only for Request for Continuing Review)
- ◯ Closed - All study activities are completed and thus requesting protocol termination (Please note: If this is option is selected, the IRB will terminate approval for research at this site).

II. **Number of Subjects**

1. What is the total number of subjects enrolled/studied at this site?

   (total):

   Please separate the total number by age range.

   0-6 years

   7-17 years

   18+ years

2. How many subjects were enrolled/studied at this site since the last review?

   (total):

   Please separate the total number by age range.

   0-6 years

   7-17 years

   18+ years

3. What is the total number of subjects taken through the consent process to date at this site? (This number should include screen failures and withdraws and anyone else who signed the consent form or otherwise agreed to participate)
   (total):

   Please separate the total number by age range.

   0-6 years

   7-17 years

   18+ years

4. Enrollment Summary: Please describe enrollment activities to date at this site as well as status of current subjects. Please be sure to include the following information, if applicable.
   - Describe types of subject enrolled, especially vulnerable populations.
   - If enrollment was permanently closed within the last approval period, include the date enrollment was closed.
   - If the clinical research remains open only for long-term follow-up of subjects, describe the status of these subjects and the nature of the follow up. (Please clearly state if these long-term follow-up activities are standard of care or research related)

5. If the study enrolls children, have any minors who will continue their participation in the study reached the age of majority in the past year (continued participation includes additional interventions, interactions, study visits, identifiable data collection, continued data availability in a registry)

   ◯ Yes ◯ Not Applicable

   ◯ No

   If yes, please provide a description of the process by which minors that have been consented for their continued participation. If subjects have not been consented justification for not doing so should be provided including clarification as to whether or not their participation in the study continues.

III. Subject Withdrawals

1. Number of subject initiated withdrawal(s) since last IRB review:

2. Please provide the reason(s) for the subject initiated withdrawal(s). (Please provide a description of any changes to the research protocol, informed consent process and/or consent document(s) that were necessary as a result of the withdrawal):

IV. Subject Complaints

1. Number of subject complaints since last IRB review:

2. Please provide the reason for the subject complaint(s). (Please provide a description of each complaint and explain how each complaint was handled.)

IV. Unanticipated Problems

1. Have any Unanticipated problems been noted sine the last IRB approval?

   ◯ Yes ◯ No

2. If yes, please provide a summary of the unanticipated problem (s).

V. Minor Protocol Deviations/Violations & Other Safety Concerns

1. Minor Protocol Deviations/Violations: Please summarize any minor protocol deviations or violations that occurred in the past year at this site. If applicable, please describe any corrective action plans implemented or to be implemented to address these issues.

2. Other Reporting: Please summarize other problems, adverse events or safety concerns that occurred in the past year at this site.

VI. Other Information

1. If applicable, please provide any other information that would be helpful in the IRBs review of this continuing review. Please ensure to attach any additional documentation to the continuing review, as needed.